EC CERTIFICATE

Certificate No 385/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, section 3 of Legislative Decree of 1997-02-24, No 46, national transposition of the Directive 93/42/EEC, we hereby certify that:

I.A.E. INDUSTRIA APPLICAZIONI ELETTRONICHE SPA

manages in the factories of:

CORMANO (MI) - VIA GRAMSCI 57 (ITA) - Italy

CORMANO (MI) - VIA F. FILZI 53 (ITA) - Italy

a full quality assurance system ensuring the conformity of the following products:

X-ray tubes

Type ref. X50; X50 AH; RTM 80 H/HS; RTM 90 H/HS; RTM 92 H/HS; RTM 101 H/HS; RTM 102 H/HS; RTC 600 HS; RTC 700 HS; X20; X20 P; X22; X40; X40 S; X45; RTM 70; RTM 78 H/HS; RTM 780 H; XM12; XM15; X40C; X22 HS; RTM 782 H/HS; RTC 1000 HS; X25; X50 H; RTM 30 HS; RTM 75 H/HS; RTM 77 H/HS; XM1016; RTC 602 HS; XM12 T; XM1016 T; XM15 T.
Trade mark IAE

CT X-ray tubes

Type ref. RTC 165; RTM 135; RTM 9800; RTM 117; RTM 103 Max.
Trade mark IAE

with the relevant essential requirements of the aforementioned national legislation transposing the Directive 93/42/EEC, from design to final inspection and testing.

Reference to IMQ files Nos: 10AA00277; 10AA00139; 10LD00008; 10AD00245; 10AE00214; 10AF00056; 10AF00187; 10AF00235; 10AI00169; 10EJ00013.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC.
Notified Body notified to European Commission under number: 0051.

Date: 2001-03-16
Updated: 2009-07-28
Substitution Date: 2008-09-30

IMQ

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".
In any case, it does not remain valid after 2011-02-09 (article 11, clause 11 of the Directive).

This is a translation of the Italian text, which prevails in case of doubts

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